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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,417	RUDAKOV ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-16 have been canceled.

Claims 17-19 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, or in the alternative, under 35 U.S.C. 103(a) as obvious over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and further in view of Barone et al., 5,360,443.

Alcime et al. disclose the invention substantially as claimed. More specifically, as to claim 17, Alcime discloses an expandable support frame (i.e., stent, for example, reference 32, column 6, line 48) having first and second end portions, a polymer sleeve (liner, for example, reference 34, column 6, line 53-55) having inner and outer surfaces, and a coating of a cell adhesion peptide (column 13, lines 56-61) carried on and

attached to at least one of the inner and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve.

However, Alcime et al. do not teach that the coating has a first layer that provides free amine groups, a second linker layer, wherein the linker layer is positioned between and covalently bonded to each of the first layer and the cell adhesion peptide coating/layer (a particular cell adhesion peptides is not yet claimed in claims 17 and 18).

However, Bhatnagar teaches that the mode of attachment of a peptide to a solid phase can be covalent linkages such as by the addition of amino acids at either the N-terminus or C-terminus to provide for binding or conjugate of the peptide to the solid phase (see col. 10, lines 37-45). Bhatnagar also teaches that the necessary domain (i.e., the peptide to be bound to the support) may include spacer arms to facilitation binding (see col. 10, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the linkage taught by Bhatnagar to bind the Alcime et al. peptide to the solid substrate because Bhatnagar teaches that this method of attachment provides the benefit of facilitating binding of the peptide to the support. The amino acids at the N-terminus, or alternatively the N-terminus disclosed by Bhatnagar is considered to be the claimed first layer that provides free amine groups. The spacer arm disclosed by Bhatnagar is considered to be the claimed second linker layer. (The molecules are considered to be in a layer because they are linking the peptide coating, or layer, of the Alcime et al. peptide to a substrate.) The spacer arm is in between the peptide layer and the layer of amine groups because it is disclosed to be in the necessary domain, i.e., the peptide, (see col. 10, line 52), and also because

Bhatnager discloses that additional amino acid residues or other moieties may be added to one or the other side of this domain to facilitate coupling or the like, so long as the essential cell-binding property of the domain is not substantially inhibited (col. 8, lines 1-3).

As to the limitation regarding the sleeve being impervious, there is not recitation as to what the sleeve is impervious in the claims nor in the disclosure of Applicants' specification, and the dictionary definition of impervious does not imply that it is impenetrable by a particular material, such as water, but just that it is impenetrable (Merriam Webster's Collegiate Dictionary, Tenth Edition). Thus, the Alcime et al. sleeve (made of polymers disclosed in column 13, lines 35-42 designed to reduce the porosity of the stent) is considered to be impervious.

Alternatively, Alcime et al. do not specifically disclose that the sleeve is impervious. However, Barone et al. teach that an aortic graft (i.e., a stent, see fig. 1) can have a coating of biological inert material such as TEFLON or porous polyurethane (col. 7, lines 16-19), and Barone et al. also teach that because of the rapid flow of blood, it is preferred that the tube (160), (i.e., the graft, or stent, col. 5, lines 55-56) be made impervious when used for repairing aneurysms which have ruptured (col. 10, lines 29-32.) The TEFLON coating is not disclosed as being impervious. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide TEFLON (not disclosed as pervious or porous) as a coating on an aortic graft or stent as taught by Barone et al., using the linking layers and peptide as taught by Alcime et al. and Bhatnagar, because Barone et al. teach that such a coating is an alternative to a

porous polyurethane, and that an impervious material is preferred when using the device for repairing aneurysms which have ruptured, because of the rapid flow of blood.

Claim 18 is a product by process claim. The product is disclosed by Alcime (see above.)

2. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and further in view of Brown et al., 6,071,305, (or in the alternative, under 35 U.S.C. 103(a) as obvious over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and Barone et al., 5,360,443, and further in view of Brown et al., 6,071,305.)

Alcime et al. in view of Bhatnagar (alternatively, in view of Bhatnagar and Barone et al.) disclose the invention substantially as claimed (see above). More specifically, Alcime teaches an expandable stent for treatment of blood vessels, wherein the stent includes therapeutic drugs such as heparin, column 13, lines 56-61. However, Alcime does not teach that the cell-adhesion peptide has the amino acid sequence presented as SEQ ID NO:1. Bhatnagar teaches SEQ ID NO:1 as a synthetic peptide substitute for natural collagen, but Bhatnagar does not teach that the synthetic peptide is used in stents such as that disclosed in the Alcime et al. reference.)

However, Brown et al. teach the use of therapeutic drugs such as heparin or *collagen on a stent* (column 2, lines 38-52, column 5, line 17 and 26).

Moreover, Bhatnagar further teaches that collagen functions as a structural protein of tissues and that it is the major fibrous element in blood vessels, see column 1,

lines 50-53, and that collagen participates in physiological interactions which include formation of complexes with other macro-molecules such as fibronectin and the modulation of cell proliferation, see column 2, lines 24-31. Bhatnagar further discloses that collagen appears to cause adverse reactions within the body, and thus synthetic peptides are provided that mimic the cell binding domain of collagen, see column 3, lines 21-32. Bhatnagar teaches that the synthetic peptide has the amino acid sequence as disclosed in column 3, lines 42-43, which is the same amino acid sequence as Applicant's claimed SEQ ID NO:1.

Since both Alcime et al. and Brown et al. references teach the use of providing a therapeutic drug such as heparin or other drugs on a stent, and Brown et al. further teach that the drug may also be collagen, it would have been obvious to provide collagen as the therapeutic drug in the Alcime et al. stent with the polymer sleeve, as would be desirable for providing the benefit of a therapeutic effect as taught by Brown.

Furthermore, it would have been obvious to provide, on the Alcime et al. stent, the synthetic peptide disclosed by Bhatnagar, as an alternative to natural collagen, because it provides the advantage of obtaining the same therapeutic effect as natural collagen but without the adverse effects of natural collagen, as taught by Bhatnagar. Moreover, the skilled artisan would have reasonable expectation of success in utilizing the Bhatnagar synthetic collagen because Brown et al. teach that collagen may be provided on stents and the skilled artisan would expect that the synthetic collagen would also be capable of being attached to a stent, given the methods of attachment disclosed by Bhatnagar as described above.

Terminal Disclaimer

The terminal disclaimer filed on August 27, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,371,980 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

Applicants' arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicants point out that Alcime teaches surface treatments to improve the tissue response of the tissue adjacent to the device and teaches use of drugs and also use of materials that encourage desirable growth of tissue. Applicants further point out that Barone teaches the use of various materials but then teaches that the tube can be made of a bio-erodable or degradable material such as collagen, so that over time, it would dissolve and a layer of endothelium, or skin, will grow providing a new lining within aneurysm. Applicants argue that the Office action fails to state why one would veer from the teachings of Alcime or Barone to modify a polymer that is otherwise unsuitable to become suitable, in other words, Applicants' claims recite a device that has a polymer material that is treated to make an inhospitable polymer material more

hospitable for endothelial cell growth. This argument is not persuasive because, as Applicants stated, Alcime teaches use of materials that encourage desirable growth of tissue, and Barone teaches use of materials that will allow for growth of endothelium, or skin, and thus both references teach the same intended result, promotion of growth of tissue. Therefore Applicants' argument regarding veering from the teachings of Alcime or Barone is not persuasive because the combination of the teachings as indicated in the grounds for rejection do not veer from the teachings of Alcime or Barone as both references teach that promotion of growth of tissue, using materials such as collagen, is desirable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Y. Lam
Primary Patent Examiner